Update on OCTGT Guidance Development Program

FDA issues guidance documents to provide the general public and stakeholders with our current thinking on topics of interest such as interpretations of our regulations, FDA expectations for content and format of investigational and marketing submissions, or inspectional expectations. FDA guidance documents do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as a recommendation, unless specific regulatory or statutory requirements are cited.

FDA's approach to guidance development, known as Good Guidance Practices (GGP) [1] dictates the general process that we use to develop and issue guidance. Principles of GGP include consideration of public and stakeholders suggestions of potential areas for guidance development, public comment on draft guidances, and periodic issuance of lists of agency guidance development activities. We use multiple approaches to collect stakeholder input including discussion at advisory committee meetings such as this one. Specific examples of guidances for which CTGTAC discussion of topics were essential to GGP process are noted in the tables that follow. The current document and the presentation on this topic at the CTGTAC meeting on April 11, 2008 are to serve to update the committee on the progress that the OCTGT has made on our portion of the current FDA Annual Guidance Agenda (71 FR 51225, September 1, 2006)[2].

The following table (Table 1) are guidances on topics related to the Guidance Agenda that have published in draft or final since September 2006.

Table 1.

Guidance Topic	Draft/Final	Issue Date	CTGTAC Discussion
Umbilical Cord Blood Intended For Hematopoietic Reconstitution in Patients With Hematological Malignancies	DRAFT	1/2007	2/2003, 3/2007
Certain Distributed and Inventoried Human Cells, Tissues, and Cellular and Tissue-	FINAL	1/2007	

[1] FDA's Good Guidance Practices are codified in 21 CFR 10.115 (http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=6911049081+4+0+0&WAISaction=retrieve) as published in the Federal Register on September 19, 200 (65FR 56468).

[2] The most recent FDA Annual Guidance Agenda is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-14549.htm

Based Products (HCT/Ps) Recovered From Who Were Improperly Tested[3]			
Preparation of Investigational Device Exemptions and Investigational New Drugs for Products Intended to Repair or Replace Knee Articular Cartilage	DRAFT	7/2007	3/2005
Validation of Rapid Microbiological Methods for Assessing Sterility of Cellular and Gene Therapy Products	2/2008	DRAFT	

The table below (Table 2) shows additional guidances that OCTGT has issued (or finalized) since September 1, 2006. Although these were not listed on the Guidance Agenda that have published in draft or final since September 2006 they cover additional topics of importance to FDA and sponsors.

Table 2.

Guidance Topic	**Draft/Final**	**Issue Date**	**CTGTAC Discussion**
Guidance for Industry: Regulation of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)- Small Entity Compliance Guide	8/2007	Immediate Implementation	
Guidance for Industry: Eligibility	8/2007	FINAL	

[3] This guidance was renamed, "Guidance for Industry: Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered From Donors Who Were Tested For Communicable Diseases Using Pooled Specimens or Diagnostic Tests"

Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products			
Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)	7/2007	DRAFT	
Guidance for Industry: Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container	1/2007	Immediate Implementation	
Guidance for Industry: Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Events	11/2006	FINAL	3/1999, 11/2000, 4/2001,10/2001
Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors	11/2006	Immediate Implementation	See above.